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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,693	02/07/2001	Jonathan B. Rothbard	578562001600	6760

25226 7590 12/19/2006  
MORRISON & FOERSTER LLP  
755 PAGE MILL RD  
PALO ALTO, CA 94304-1018

EXAMINER
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JONES, DAMERON LEVEST

ART UNIT	PAPER NUMBER
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1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/19/2006	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/779,693	<b>Applicant(s)</b> ROTHBARD ET AL.	
	<b>Examiner</b> D. L. Jones	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 34-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **ACKNOWLEDGMENTS**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/19/06 has been entered.

2. The Examiner acknowledges receipt of the amendment filed 10/19/06 wherein claims 1-33 and 40 are canceled and claims 34-39 are amended.

**Note:** Claims 34-39 are pending.

## **RESPONSE TO APPLICANT'S AMENDMENTS/ARGUMENTS**

3. The Applicant's arguments and/or amendment filed 10/19/06 to the rejection of the claims made by the Examiner under 35 USC 103 and/or double patenting have been fully considered and deemed persuasive for reasons of record. Therefore, the said rejections are hereby withdrawn.

## **CLARIFICATION OF THE RECORD**

4. Review of US Patent Nos. and 6,730,293 deemed necessary the above rejection because of overlapping subject matter. Thus, double patenting rejections are necessary.

## **NEW GROUNDS OF REJECTION**

### **Double Patenting Rejection**

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 34-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 106 and 120-122 of U.S. Patent No. 6,593,292. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compositions comprising a biologically active agent in combination with a delivery enhancing transporter that containing sufficient guanidino and amidino moieties. In particular, the instant invention discloses that typically, the delivery

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enhancing transports have from 6-50 guanidino or amidino moieties. Thus, a skilled practitioner in the art would recognize that since the delivery-enhancing transporter of the patented invention contains 5-25 arginine residues, the transporter contains 5-25 guanidino and amidino moieties. In addition, a skilled practitioner in the art would recognize that both inventions are directed to compositions wherein the biological active agent is an antiviral, antibacterial, antifungal, antiproliferative (i.e., antineoplastic), analgesic, or immunosuppressive agent (i.e., cyclosporine, see claim 122). The claims differ in that the instant invention list specific biologically active agents; however, it would be obvious to one of ordinary skill in the art at the time the invention was made that the claims of the instant invention are encompassed by the patented claims which broadly claim the classes of biologically active agents that are listed in the pending claims. Furthermore, since the claims contain 'open' claim terminology (i.e., 'comprising'), additional components may be present in the composition.

7. Claim 38 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-8 of U.S. Patent No. 6,730,293. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compositions comprising a biologically active agent in combination with a delivery enhancing transporter that containing sufficient guanido and amidino moieties. In particular, the instant invention discloses that typically, the delivery enhancing transports have from 6-50 guanidino or amidino moieties. Thus, a skilled practitioner in the art would recognize that since the delivery-enhancing transporter of the patented invention contains 5-25 arginine residues, the transporter contains 5-25 guanidino and amidino moieties. In addition, a skilled practitioner in the art would recognize that both inventions are directed to compositions wherein the biological active agent is immunosuppressive agent (i.e.,

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cyclosporine, see patented claim 1). Thus, it would be obvious to one of ordinary skill in the art at the time the invention was made that the claims of the instant invention are encompassed by the patented claims which broadly claim the classes of biologically active agents that are listed in the pending claims. The claims differ in that the patented claims contain additional components. A skilled practitioner in the art would recognize that because the claims of the instant invention contain 'open' claim language (i.e., 'comprising'), additional components may be present in the composition.

#### **COMMENTS/NOTES**

8. It is once again noted that no prior art has been cited against the instant invention. The claims are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious the compositions comprising the deliver enhancing transporter and specific biologically active agents as set forth in the pending claims.


9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
D. L. Jones  
Primary Examiner  
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December 8, 2006